Complete Summary

GUIDELINE TITLE

Procedure guideline for palliative treatment of painful bone metastases.

BIBLIOGRAPHIC SOURCE(S)

Silberstein EB, Buscombe JR, McEwan A, Taylor AT Jr. Procedure guideline for palliative treatment of painful bone metastases, 3.0. Reston (VA): Society of Nuclear Medicine; 2003 Jan 25. 8 p. [17 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Society of Nuclear Medicine. Procedure guideline for bone pain treatment, 2.0. Reston (VA): Society of Nuclear Medicine; 1999 Feb. 26 p. (Society of Nuclear Medicine procedure guidelines; no. 2.0).

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Bone pain due to osteoblastic metastases

GUIDELINE CATEGORY

Evaluation
Treatment

CLINICAL SPECIALTY

Nuclear Medicine
Oncology
Radiology

INTENDED USERS

Allied Health Personnel
Physicians

GUIDELINE OBJECTIVE(S)

- To assist nuclear medicine practitioners in evaluating patients who might be candidates for ^{32}P-sodium phosphate, ^{89}Sr-chloride, or ^{153}Sm-lexidronam (^{153}Sm-EDTMP) radiopharmaceutical treatment of bone pain resulting from osteoblastic metastases
- To provide information for performing this treatment and to assist in understanding the sequelae of therapy

TARGET POPULATION

Patients with bone pain resulting from a metastatic malignancy that has involved multiple skeletal sites and has evoked an osteoblastic response on bone scintigraphy

INTERVENTIONS AND PRACTICES CONSIDERED

Radiopharmaceutical treatment of bone pain with ^{32}P-sodium phosphate, ^{89}Sr-chloride, or ^{153}Sm-lexidronam

MAJOR OUTCOMES CONSIDERED

- Palliation of bone pain
- Safety/adverse effects of treatment

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Literature searches were performed. In addition, references known to experts and references from the nuclear medicine community were considered.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Not stated

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Drafts of the guideline were submitted to members of the Guideline Development subcommittee (methodologists) and the Task Force (subject experts). These reviewers indicated on a line-by-line basis any suggestions or recommendations for the revision of the guideline. The percentage of agreement for all reviewers was calculated for each revision and compiled by the Society of Nuclear Medicine (SNM) central office. It is expected that the percentage of agreement will increase with each revision.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

When the Task Force and Guideline Development Subcommittee completed their edits, draft procedure guidelines were distributed to the Society of Nuclear Medicine (SNM) Sample Review Group for comment. (The SNM Sample Review

Group is a cross-section of approximately 100 nuclear medicine practitioners representing every field of specialization).

The guideline was approved by the SNM Commission on Health Care Policy, the Board of Directors, and the House of Delegates.

The updated guideline was approved January 25th, 2003.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Background Information and Definitions

A. Definitions
   1. ^{89}Sr therapy means the intravenous injection of the radionuclide ^{89}Sr as strontium chloride. ^{89}Sr-chloride emits a beta particle with maximum energy 1.46 MeV, mean energy 0.58 MeV, average soft-tissue range 2.4 mm, and 0.01% abundant gamma emission with a photopeak of 0.91 MeV. It has a 50.5-d physical half-life.
   2. ^{153}Sm-lexidronam therapy means the intravenous injection of the radionuclide ^{153}Sm chelated to ethylene diamine tetramethylene phosphonate. ^{153}Sm emits a beta particle with maximum energy 0.81 MeV, mean energy 0.23 MeV, average soft-tissue range 0.6 mm, and 28% abundant gamma emission with a photopeak of 0.103 MeV. It has a 1.9-d physical half-life.
   3. ^{32}P therapy means the intravenous injection or oral administration of the radionuclide ^{32}P as sodium phosphate. ^{32}P-sodium phosphate emits a beta particle with maximum energy of 1.71 MeV, mean energy 0.70 MeV, average soft-tissue range 3.0 mm, and no gamma emission. It has a 14.3-d physical half-life.
   4. "Osteoblastic" or "osteoblastic metastases" means a focus or foci of increased activity on bone scintigraphy caused by osseous reaction to tumor in bone. These may appear osteoblastic or osteolytic on radiographs.

B. Background

Intravenous injection of ^{89}Sr-chloride and ^{153}Sm-lexidronam and intravenous or oral administration of ^{32}P-sodium phosphate have been approved by the U.S. Food and Drug Administration (FDA) for the treatment of bone pain resulting from osteoblastic metastasis as defined by bone scan. Physicians involved in treating such patients should have an understanding of the natural history of the disease process and should be able to collaborate closely with the physician (or group of physicians) handling the overall management of the patient's disease.

The administration of these agents falls under the guidelines of the Nuclear Regulatory Commission (NRC), Title 10 CFR Part 35.300 or Agreement State Institutional License. Institutional licenses must specifically list individuals licensed to use Section 35.300 materials.

As other radiopharmaceuticals are approved by the FDA for the treatment of bone pain resulting from osteoblastic metastases, they will be added to the guideline.

Common Indications

^{32}P-sodium phosphate, ^{89}Sr-chloride, and ^{153}Sm-lexidronam (and the other unsealed beta or conversion electron-emitting radiopharmaceuticals under development or approved in countries outside the United States, e.g., ^{186}Re-etidronate) are indicated for the treatment of bone pain resulting from a metastatic malignancy that has involved multiple skeletal sites and has evoked an osteoblastic response on bone scintigraphy. Where there is danger of either spinal cord compression from vertebral metastases or pathologic fracture in the extremities, ^{32}P-sodium phosphate, ^{89}Sr-chloride, or ^{153}Sm-lexidronam therapy should only be used in conjunction with other forms of management directed at these complications and after management of the acute presentation.

Procedure

The detailed procedure recommendations in the guideline address the following areas: facility/personnel; patient preparation; information pertinent to performing the procedure (i.e., important data that the physician should have about the patient at the time the exam is performed and interpreted); instructions for patients; precautions; information regarding the radiopharmaceutical (i.e., ranges of administered activity, organ receiving the largest radiation dose, effective dose), image acquisition; guidelines for measuring the activity of ^{32}P-Sodium Phosphate, ^{89}Sr-Chloride, or ^{153}Sm-Lexidronam to be administered; interventions; processing; interpretation/reporting; quality control; and sources of error.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence supporting the recommendations is not specifically stated.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

^{32}P-sodium phosphate, ^{89}Sr-chloride, or ^{153}Sm-lexidronam has a 25 to 80% probability (depending on how the subjective pain response is measured) of reducing bone pain resulting cancer spread in bone, but the chance of relieving pain completely is low but real.

POTENTIAL HARMS

The patient should be told that the two most common side effects are:

- An increase in bone pain ("flare") occurring most often within 72 hours of injection but, rarely, up to 21 days after injection and lasting 2 to 5 days. Flare is unusual after the second week and can be treated by increasing doses of analgesia, if required.
- The likelihood that the leukocyte and platelet counts may decrease by 30 to 70% of baseline values or possibly to even to lower levels which could lead to infection if leukocytes are too low or bleeding if the platelets are too low. Bleeding or the risk of bleeding could require platelet transfusion. Marrow replacement by tumor, ^{32}P-sodium phosphate, ^{89}Sr-chloride, or ^{153}Sm-lexidronam therapy, chemotherapy and external beam radiotherapy have additive effects on myelosuppression, and the presence of two or more of these risk factors increases the possibility of clinically significant marrow suppression.

CONTRAINDICATIONS

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Pregnancy and breast feeding are absolute contraindications to therapy.

QUALIFYING STATEMENTS

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- The Society of Nuclear Medicine has written and approved guidelines to promote the cost-effective use of high quality nuclear medicine procedures. These generic recommendations cannot be applied to all patients in all practice settings. The guidelines should not be deemed inclusive of all proper procedures or exclusive of other procedures reasonably directed to obtaining the same results. The spectrum of patients seen in a specialized practice setting may be quite different than the spectrum of patients seen in a more general practice setting. The appropriateness of a procedure will depend in part on the prevalence of disease in the patient population. In addition, the resources available to care for patients may vary greatly from one medical facility to another. For these reasons, guidelines cannot be rigidly applied.
- Advances in medicine occur at a rapid rate. The date of a guideline should always be considered in determining its current applicability.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

End of Life Care
Living with Illness

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Silberstein EB, Buscombe JR, McEwan A, Taylor AT Jr. Procedure guideline for palliative treatment of painful bone metastases, 3.0. Reston (VA): Society of Nuclear Medicine; 2003 Jan 25. 8 p. [17 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1999 Feb (updated 2003 Jun 20)

GUIDELINE DEVELOPER(S)

Society of Nuclear Medicine, Inc - Medical Specialty Society

SOURCE(S) OF FUNDING

Society of Nuclear Medicine (SNM)

GUIDELINE COMMITTEE

Task Force

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Authors: Edward B. Silberstein, MD (University of Cincinnati Medical Center, Cincinnati, OH); John R. Buscombe, MD (Royal Free Hospital, London, UK); Alexander McEwan, MD (Cross Cancer Institute, Edmonton, Alberta, Canada); and Andrew T. Taylor, Jr., MD (Emory University School of Medicine, Atlanta, GA)

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

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GUIDELINE AVAILABILITY

Electronic copies: Available from the Society of Nuclear Medicine (SNM) Web site.

Print copies: Available from SNM, Division of Health Care Policy, 1850 Samuel Morse Dr, Reston, VA 20190-5316; Phone: 1-800-513-6853 or 1-703-326-1186; Fax: 703-708-9015; E-Mail: ServiceCenter@snm.org.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Society of Nuclear Medicine. Procedure guideline for guideline development. Reston (VA): Society of Nuclear Medicine; 2001 Jun (version 3.0). Electronic copies: Available from the Society of Nuclear Medicine Web site.
- Society of Nuclear Medicine. Performance and responsibility guidelines for NMT. Reston (VA): Society of Nuclear Medicine; 2003. Electronic copies: Available from the Society of Nuclear Medicine Web site.

Print copies: Available from SNM, Division of Health Care Policy, 1850 Samuel Morse Dr, Reston, VA 20190-5316; Phone: 1-800-513-6853 or 1-703-326-1186; Fax: 703-708-9015; E-Mail: ServiceCenter@snm.org.

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on May 20, 1999. It was verified by the guideline developer as of May 26, 1999. This summary was updated by ECRI on April 14, 2005.

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Date Modified: 9/25/2006